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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/267,511	03/12/1999	DOUGLAS E. BRENNEMAN	015280-37700	7130

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EXAMINER
CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
1646	24

DATE MAILED: 01/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/267,511	BRENNEMAN ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-13 and 15-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-13 and 15-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. Claims 1 and 18 have been amended as requested in the amendment of Paper No. 23, filed on November 13, 2002. Claims 1, 4-13 and 15-18 are pending and under examination in the instant application.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on November 13, 2002 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

5. Claims 1, 4-13 and 15-18 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for inhibiting fetal demise, decreased fetal birth weight and decreased fetal brain weight in a subject exposed to alcohol *in utero* by administration of ADNF polypeptides prior to alcohol exposure, does not reasonably provide enablement for a method for reducing any condition associated with fetal alcohol syndrome by administration of ADNF polypeptides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims for the reasons of record in section 6 of Paper No. 21.

Applicant traverses the rejection on the premises that the instant specification is fully enabled for the full scope of a method for reducing a condition associated with fetal alcohol syndrome by administration of an ADNF polypeptide because "the rodent model described in the specification correlates with the claimed method of treating fetal alcohol syndrome" and, further, because "all tested conditions that are associated with the fetal alcohol syndrome are reduced by administration of ADNF peptides", therefore, any condition associated with the syndrome would also be similarly reduced (section 1 on pages 4-5 of the Response). This has not been found to be persuasive for the following reasons.

Applicant's reliance on *In re Brana*, 51 F.3d 1560,1566, 34 USPQ2d 1436 ,1441 (Fed. Cir. 1995) is misplaced. That court decision determined that a compound which belonged to a family of compounds known to have anti-tumor activity, which is a common and well established specific and substantial utility for that family of compounds, would be reasonably expected to have anti-tumor activity in light of positive *in vitro* data with respect to that particular compound since that data has proven to be an indicator of anti-cancer activity by other members of that family. In the instant case, by using an art-accepted rodent model that correlates with fetal alcohol syndrome (FAS), one skilled in the art would at most have reasons to expect only similarity between changes in or of certain conditions associated with the syndrome in rodents and humans. Therefore, based on the information provided in the instant specification, a skilled artisan would reasonably conclude that because intraperitoneal administration of ADNF polypeptides prior to alcohol exposure inhibited fetal demise, decreased fetal birth weight and decreased fetal brain weight in mice exposed to alcohol *in utero*, then similar treatment under the same conditions would be beneficial to humans. However, the instant claims are broadly drawn

to a method for reducing any condition associated with fetal alcohol syndrome by administration of ADNF polypeptides. Applicant fails to provide any evidence or sound scientific reasoning that would support a conclusion that the limited information on beneficial effects of administration of ADNF for reduction of some symptoms of FAS would be sufficient to substantiate grounds for general reduction of any condition associated with fetal alcohol syndrome.

It is obvious and well known in the art that no animal model can be totally and unconditionally predictive for any human disease, disorder or a complex condition in general and, therefore, it can be accepted only to a certain degree of similarity. In the article by Webster et al. (Exhibit 2 of the Declaration of Brenneman) it is clearly stated that ""[a]nimal studies of the effect of alcohol on embryonic development have varied significantly in methodology and, subsequently, results. [...] In some cases malformations of the eyes, brain or limbs have been observed. Acute alcohol exposure to alcohol on one or more days of gestation has resulted only in fetal growth and skeletal retardation in the rat [...], and increased fetal mortality, coloboma of the iris and forelimb ectordactyly in mice" (see the abstract). Thus, it is clear that exposure to alcohol manifests differently in different animals. There is no indication in the prior art or the instant specification that the improvement of one set of conditions associated with FAS in mice is predictive of any or all of the fetal alcohol symptoms in humans or any other animal.

Applicant's assertion that "[t]he Examiner improperly imported a limitation from an example into the claims" (page 6, last paragraph of the Response) has been found to be unsubstantiated. Applicant submits that "the Examiner asserts that Applicants are entitled only to claim scope that corresponds to an exemplified administration treatment of fetal alcohol syndrome with ADNF peptides, e.g., administration of ADNF peptides 30 minutes prior to

alcohol ingestion" (page 7, last paragraph of the Response). The scope of the enablement for claims 1, 4-13 and 15-18 has been established as "being enabled for a method for inhibiting fetal demise, decreased fetal birth weight and decreased fetal brain weight in a subject exposed to alcohol in utero by administration of ADNF polypeptides prior to alcohol exposure", see the beginning of the text of the instant rejection and also in section 6 of Paper No. 21. Claims 1, 4-13 and 15-18, as written, broadly encompass a method for reducing a condition associated with fetal alcohol syndrome by administration of ADNF regardless of the time of administration, while the teachings of the specification show that the treatment is effective only when ADNF is administered prior to alcohol consumption. Applicant's assertion that "the timing of administration of ADNF peptides would not require undue experimentation by one skilled in the art" (page 8, first paragraph of the Response) is not supported by any facts of record. On the contrary, the testing whether the proposed treatment is actually effective when administered after alcohol consumption by a subject or testing what is the time frame for the effectiveness of the treatment is not routine experimentation but undue burden for one skilled in the art in order to be able to practice the full scope of Applicant's invention, as currently claimed.

Conclusion

6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original

signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.
January 21, 2003 OC

JOHN ULM
PRIMARY EXAMINER
GROUP 1600